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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,714	10/07/2005	Christian Schafer	232089	5699

23460 7590 07/29/2008

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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,714	SCHAFER ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant amendment filed on 04/21/2008 is acknowledged. The claim for priority under 35 U.S.C 119 is also acknowledged including the receipt of the certified copies to the two priority documents.

Claims 1-21 are being considered on the merits.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walsh (US 4,309,344; hereinafter R1) in view of Nielsen et al. (US 5,989,600; hereinafter R2).

3. R1 discloses a process for the production of a protein isolate from defatted vegetable protein material (Abstract).

4. R1 outlines the process in which the soybeans or vegetable protein material are preferably defatted and the oil is extracted to leave the soybean meal or flakes. It is preferable to remove the oil by solvents such as hexane or azeotropes which have been conventional for the oil extraction (Col. 4, lines 25-34).

5. R1 teaches grinding the vegetable protein material (soybean flakes) which includes protein , sugars, fibers and other materials and placing the flakes in an aqueous bath at a pH of about 6.5 and preferably between 7.0 and 10.0. To elevate the

pH of the solution sodium hydroxide, potassium hydroxide and calcium hydroxide may be used if desired (Col. 4, lines 40-52).

6. R1 discusses that a pH of above about 7.0 is generally preferred for a better solubilization of proteins (Col. 4, lines 54-60).

7. R1 teaches the ratio of the extractant to the vegetable protein material to be between 5-20 to 1 and preferably 10:1 (Col. 4, lines 6—63).

8. R1 discloses the extraction temperature at ambient to 120F and preferably at 90F. (Col. 5, lines 5-7).

9. R1 adds that the time required for the extraction may be from 5 to 120 minutes and preferably 30 minutes (Col. 5, lines 10-12).

10. R1 discloses a second extraction of the insoluble and residual solids from the first extraction step (Col. 5, lines 15-17).

11. R1 teaches adjusting the pH of the combined extracts from first and second extractions to preferably between 4.4 and 4.6 which can be done using common food grade acid reagent (Col. 5, lines 48-63).

12. R1 teaches neutralizing the precipitate to about pH 7.0 before drying it to obtain a neutral dried product (Col. 6, lines 27-31).

13. R1 recommends spray drying the protein product for a highly water dispersible product (Col. 6, lines 44-51).

14. R1 is silent regarding the lipase treatment of the isolated protein.

15. R2 teaches treating the vegetable protein source with an efficient amount of one or more enzymes selected from the group consisting of lipolytic enzymes (Col. 5, lines 19-21).

16. R2 teaches using any triacylglycerol lipase for the treatment of the vegetable protein source (EC 3.1.1.3) (Col. 5, lines 27-28).

17. R2 discusses that the proteinaceous vegetable subjected to the method of their invention may be provided in any form including soybeans, defatted soy flakes, soy meal, soy concentrate and isolate (Col. 2, lines 54-60).

18. R2 teaches inactivating the enzyme by heating the mixture to above 85ºC. (Col. 3, lines 26-30)

19. R2 discloses that the vegetable protein source may be a legume, a cereal, a composite plant or a crucifera. Legume sources may be soy bean, faba bean, pea and lupine. Cereal sources may be wheat, corn, barley, rye, oat, rice, sorghum, sesame. Composite plant may be sunflower and crucifera may be rape seed (Col. 2, lines 42-52).

20. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to modify the teachings of Walsh by treating the plant protein with lipase as taught by Nielsen. One would have done so to reduce the residual lipid content of the protein material by hydrolyzing it and subsequently extracting it from the protein material causing an organoleptic improvement in the product. Absent any evidence to contrary and based on the teachings of the combined cited references, there would have been a reasonable expectation of success in producing a product with lower lipid content.

Response to Arguments

Applicants' arguments have been fully reviewed and considered. The reasoning, by applicants, to establish unobviousness of the claimed invention is not persuasive.

1. Applicants argue that the disclosures by R1 do not include using lipase for reducing the phospholipid content of the product and that the disclosure by R2 does not remedy the deficiency of R1 due to the fact that the product disclosed by R2 is a hydrolysate and not a protein preparation as presently claimed. In response to this argument:

a. The presently claimed invention is focused on a protein isolate which is produced from e.g. soybeans which have been deoiled by a solvent such as hexane. The deoiled flakes are then extracted by water at an alkaline pH to facilitate the extraction process. Water extraction may be a single or a double extraction as taught by R1. Please refer to paragraphs 3-13 above which disclose a protein isolate similar to the presently claimed invention. However, the use of lipase in the preparation of the protein isolate is not disclosed or taught by R1.

b. The examiner agrees that the product disclosed by R2 is in fact a hydrolysate which uses more or less the same raw materials as claimed in the present invention and as used by R1. The process comprises 3 steps. Steps one and two may be done concomitantly or consecutively. Step three is a hydrolysis by a lipase (EC 3.1.1.3). This hydrolysis is being performed on a proteinaceous material.

c. The applicants are using lupine seed flakes deoiled by hexane. The flakes are extracted twice followed by neutralization and then spray dried to obtain a dried product. This part of the process is basically equivalent to the process disclosed by R1.

d. In the course of the process as taught by R1, two extracts, from two extractions, are combined (R1, col. 7, lines 1-2) and the extracted protein is precipitated at its isoelectric pH (about 4.6). The whey remaining after this precipitation contains all impurities including lipids. Some lipids will naturally be left in the precipitated protein either as entrapped lipids or in association with proteins which are now at their isoelectric form. To rid the protein of such lipid fractions, one skilled in the art knows that solubilization of the remaining lipid fraction can be facilitated by lipases. Those skilled in the art also know that certain lipases have the phospholipase activity so the phospholipids will be affected as well. As a result choosing to treat the protein with a lipase is obvious to one of ordinary skill in the art. R2 is treating a hydrolysate with lipase for the same purpose of breaking down the lipids, however, to get rid of the phosphates; R2 employs phytase because of the nature of the product. In the presently claimed invention, the hydrolyzed lipid is washed away upon precipitating the product. Therefore it would have been obvious to one of ordinary skill in the art to modify R1 with the lipase of R2 in order to reduce the residual phospholipids content of the protein material to amounts, including less than or equal to 0.4% as presently claimed, in order to cause an organoleptic improvement in the product.

e. The lipid content of the starting raw material will depend on the process by which the raw material was deoiled. The deoiled flakes can be made to contain minimal

amounts of lipids in which case, the protein isolate prepared from them will inherently be low lipid materials. Therefore, the limitation of claim 1 that the phospholipid content of the protein isolate is ≤ 0.4 may even be met if you start with very low lipid content in the flakes just by a regular extraction specifically when considering the extraction using alkaline solution and the interaction of lipids with alkaline solution.

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/Callie E. Shosho/
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